REMARKS:

Applicant has carefully studied the non-final Examiner's Action mailed May 16, 2006. These explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Claim Rejections 35 U.S.C. § 102

Applicant acknowledges the quotation of 35 U.S.C § 102(e).

Claims 1, 2, 6, 8, 10, 21, 22 and 24-28 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,678,558 B1 (Dimmer et al.).

The Office states that Dimmer teaches a method for facilitating the delivery of a desired molecule into a target tissue consisting essentially of introducing a molecule into a target tissue comprising a cell, applying an electric field to the target tissue wherein the application of the electric field consists of a single continuous electric field (claims 1, 21) or a plurality of substantially continuous electric fields (claim 24) in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell (claims 1, 21, 24); wherein the duration of the applying step is in the range of 200ms to 100 sec (claims 2 and 22); wherein the electric field comprises a pulse comprising a combination of at least two of the indicated pulse waveforms (claim 26); wherein the injection step if by syringe injection (claims 8, 24); wherein the target tissue is skin or tumor tissue (claims 10, 28).

More specifically, the Office states that Dimmer et al. teaches a method for delivering an agent such as a nucleic acid into a cell of a target tissue (such as skin or tumor tissue) using an electric signal that has a bipolar waveform (e.g., see abstract), wherein the agent is injected directly by needle and syringe (e.g., see column 2 lines 24-27), wherein the electric signal can have a bipolar, square or sinusoidal waveform (e.g., see column 5, lines 35-36; column 8, lines 17-30), wherein the electric signal can be a plurality of electric signals (e.g., see column 9, lines 10-16) wherein the electric field(s) are in the range of 1mv/cm to 200V/cm (e.g., 25V/cm or 100V/cm see column 10, lines 29-42); wherein the electric field is applied for a duration of 200ms-20 minutes (e.g., most preferably about 50μs-400ms see column 10, lines 54-60; column 13, lines 7-19; column 14, lines 21-23; column 23, lines 1-11; column 24, lines 43-50; column 29, lines 12-15; claims 1, 10, 11, 16, 17, 25).

In response to the Applicant's arguments filed on 08/16/2006, the Office states that Dimmer explicitly teaches at col. 29, lines 41-44, "The total electroporation signal duration is preferably less than about 10 seconds, more preferably about 30μs-10 seconds, even more preferably about 30μs-1ms and most preferably about 50μs-400ms". Additionally, the Office states that Dimmer teaches that the electroporation signal is not only limited to a bipolar signal, but may also be a monopolar signal. Therefore, taken as a whole, the Office concludes that Dimmer teaches administering an electroporation signal for a total electroporation signal duration in the claimed range of 200ms to 20 minutes, wherein the electroporation signal can be a monopolar signal. As such, the Office concludes that Dimmer teaches administration of a monopolar signal for a total signal duration of preferably less than about 10 seconds, more preferably about 30μs-10 seconds even more preferably about 30μs-1ms and most preferably about 50μs-400ms, which thus anticipates the instant claims.

Applicant respectfully disagrees with the finding of the Office.

Claims 1, 21 and 24 of the present invention describe the application of a "continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes". As such, a continuous electric field of the present invention is a *single* continuous pulse in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes.

Dimmer does not describe applying an electric field consisting of a single continuous electric field in the range of 1mV/cm to 200V/cm for a duration of 200ms to 20 minutes. In contrast, Dimmer describes applying an electroporation signal having a total electroporation signal duration that is preferably less than about 10 seconds, more preferably about 30μs-10 seconds, even more preferably about 30μs-1ms and most preferably about 50μs-400ms, wherein the total electroporation signal duration is comprised of the individual durations of each of the plurality of therapeutic electrical signals within the electroporation signal, wherein each of the plurality of therapeutic electrical signals has a pulse duration of less than about 50μs.

Applicant believes that the Office is improperly combining the parameters of the "total electroporation signal duration" and the "therapeutic electrical signals" as described by Dimmer to arrive at the claim limitations of the instant invention.

Therapeutic electrical signals, as described by Dimmer at col. 10, line 11-19, preferably have a pulse duration of less than about 50μs, more preferably have a pulse duration of less than about 12.5μs and most preferably a pulse duration of less than about 5μs. Dimmer then describes at col. 10, beginning at line 48, that the total electroporation signal duration is the sum of each electroporation signal included

in a single electroporation therapy treatment and that the total electroporation signal duration is preferably less than about 10 seconds, more preferably about 30μs-10 seconds, even more preferably about 30μs-1ms and most preferably about 50μs-400ms. As such, a *single* pulse of the Dimmer reference is described as having a duration of less than about 50μs, and it is a plurality of *single* pulses in combination that equal the total electroporation signal duration that is preferably less than about 10 seconds. Additionally, even if there was only a single pulse within the total electroporation signal duration of Dimmer, according to Dimmer that single pulse would have a duration of less than about 50μs and as such, the total electroporation signal duration in that case would only be equal to the duration of that one single pulse which would be less than about 50μs. In summary, Applicant believes that Dimmer teaches an electroporation treatment wherein the duration of the total electroporation signal is less than about 10 seconds and wherein the electroporation treatment comprises a plurality of single pulses, each of the single pulses having a duration that is less than about 50μs.

Additionally, the Office has taken the parameters of the "total electroporation signal duration" of Dimmer and applied them to the present invention. However, the "total electroporation signal duration" is a duration, which means it describes an interval in time, which is not equivalent to a pulse duration. The "total electroporation signal duration" described by Dimmer is preferably less than about 10 second, but the "pulse duration" described by Dimmer is preferably less than about 50μs. The present invention claims a single continuous electric field (i.e. pulse) having a duration (i.e pulse duration) between 200ms and 20 minutes. As such, Dimmer does not anticipate the claimed pulse duration range of the present invention.

While Applicant admits that the language used by Dimmer is somewhat inconsistent throughout the specification, more support for the argument presented by the Applicant can be found in the claims of the Dimmer reference. For example, claim 1 of Dimmer cites a therapeutic electrical signal. Claim 5 further defines the therapeutic electrical signal, in which Dimmer states that the therapeutic electrical signal is comprised of 1 to about 1,000,000 pulses. Claim 6 further defines the pulses of claim 5 by stating that each pulse has a duration of about 2 to about 50μs. Claim 7 and claim 8 further define the therapeutic electrical signal in which Dimmer states that the plurality of pulses of the therapeutic electrical signal have a total pulse duration of less than about 10 seconds or between about 30ms to 1 second.

Accordingly, Applicant believes that Dimmer clearly is describing an electroporation treatment in which a plurality of short pulses (<50μs) are used in combination to elicit electroporation, which is in contrast to the present invention which suggests and claims an electroporation treatment consisting of a

single, continuous pulse having a long duration (>200ms) to elicit electroporation. Therefore, taken as a whole, Dimmer does not teach administering an electroporation signal consisting of a single, continuous electric pulse for a duration of 200ms-20 minutes, but instead describes administering an electroporation signal consisting of a plurality of electric pulses which are each less than about 50μs such that the total duration of the electroporation is less than about 10 seconds.

The Office states that Dimmer describes at col. 14, lines 21-23, an agent movement signal having a potential of about 5V-200V and more preferably about 10V-100V, having a duration of the agent movement signal of preferably about 100μs-10 seconds.

The present invention claims applying an electric field to the target tissue wherein the application of the electric field consists of a single continuous electric field (claims 1, 21) or a plurality of substantially continuous electric fields (claim 24) in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell. As such, the single continuous electric field of the present invention effects a change is porosity of the cell in the target tissue.

By contrast, the agent movement signal as described by Dimmer does not effect a change in porosity of the cell in the target tissue, but is only effective in moving the agent closer to the cell that is being targeted by the electroporation signals. Accordingly, the agent movement signal as described by Dinner does not anticipate a continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell as disclosed and claimed by the present invention.

In the Office Action mailed on November 2, 2006, the Office states that the agent movement signal taught by Dimmer meets the voltage and duration limitations of the claims. As such, the Office concludes that the administration of the "agent movement signal" as described by Dimmer, would necessarily have the same result as the claimed method. The Office states that since the agent movement signal taught by Dimmer meets the voltage and duration limitations of the claims, it must have the same effect on the cells and thus, application of the agent movement signal, as described by Dimmer would necessarily result in a change in the porosity of the cell sufficient to facilitate entry of the desired molecule into the cell. Additionally, the Office cites MPEP 2112.01 which teaches, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced

by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established".

Applicant respectfully disagrees with this conclusion by the Office. Claim 1 is a process claim, not a product claim, and as such Applicant does not believe that the Office has properly applied MPEP 2112.01, but should instead apply the guidelines specified under MPEP 2112.02. In accordance with MPEP 2112.02, new and unobvious uses of old structures and compositions may be patentable. The prior art reference to Dimmer clearly states that the combination of the voltage and duration limitations of the agent movement are not sufficient to cause electroporation of the cells. Applicant points out that there are numerous combinations of pulse durations and voltage levels possible with the ranges described by Dimmer. However, none of the combinations of pulse durations and voltage levels described by Dimmer would be effecting if electroporating the cells.

By contrast, claim 1 of the present invention claims the application of an electric field consisting of a single continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell of the target tissue in response to the application of the electric field, the change in porosity sufficient to facilitate entry of a desired molecule into an interior of the cell. As such, the combination of pulse duration and voltage level as taught by the present invention is sufficient to effect electroporation of the cells. As such, Applicant believes that a discovery of a new use for an old structure based on unknown properties of the structure is patentable to the discoverer as a process of using in accordance with MPEP 2112.02. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957).

For the reasons stated above, Applicant believes that independent claims 1 and 21 are not anticipated by Dimmer et al. and are believed to be in condition for allowance. More specifically, neither the "total electroporation signal" or the "agent movement signal" of Dimmer anticipate the continuous electric field in the range of 1mV/cm to 200V/cm applied for a duration of 200ms to 20 minutes and effecting a change in porosity of the cell in the target tissue in response to the application of the electric field wherein the change in porosity is sufficient to facilitate entry of the desired molecule into the cell as disclosed and claimed by the present invention.

Claims 2, 6, 8 and 10 are dependent upon claim 1, and are therefore allowable as a matter of law. Claims 22 and 24-28 are dependent upon claim 21, and are therefore allowable as a matter of law.

By cancellation or amendment of these claims, applicants only wish to advance prosecution of the present application. Applicants reserve the right to prosecute one or more subject matter in the original

claims in one or more continuation applications and that equivalence to these claims have not been relinquished by these amendments.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,
SMITH & HOPEN

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Reg No. 46,457

CERTIFICATE OF FACSIMILE TRANSMISSION
(37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this Amendment J is being transmitted by facsimile to the United States Patent and Trademark Office, Central Fax Center, Art Unit 1635, Attn: Jon E. Angell, (571) 273-8300 on May 2, 2007.

Dated: May 2, 2007

Deborah Preza